

## **REMARKS/ARGUMENTS**

A petition for a two month extension of time and authorization to charge the fee, is submitted herewith.

### **I. Rejections Under 35 U.S.C. 112**

Examiner has rejected claims 4-7 as being indefinite under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claims 4-7 to specify that the weight % is “based upon the total lens forming components in the reaction mixture”. Support for the amendment may be found at page 7, lines 27-28.

### **II. Rejections Under 35 U.S.C. 103(a)**

Examiner has rejected claims 1, 3-10, 12-15 and 28-29 as being unpatentable under 35 U.S.C. 103(a) over Sakuma et al., (US 5,213,801) in view of Nochumson, (US 4,542,200) and in further view of Vanderlaan et al., (US 5,998,498).

In the present invention, the Applicants have surprisingly found that ratio of weight% silver to the weight% ligand monomer is critical for achieving the desired levels of antimicrobial efficacy in the recited antimicrobial lenses. Table 2 on page 23, clearly shows that as the silver:ligand ratio increases, the efficacy of the resultant lens also increases. This is neither disclosed nor suggested in the cited references.

Sakuma et al. discloses contact lenses containing antibacterial ceramic materials, all of which are inorganic (see column 1, lines 55- 59). Sakuma does not disclose or suggest using any organic or polymeric material, let alone the specific monomers recited in Formula I, II, III or IV of claim 1. Sakuma et al. also fails to suggest that the ratio of silver to ligand might be important.

Nochumson discloses polyacrylamide gel electrophoretic carrier medium which are “highly resistant to shrinking and cracking”. There is no disclosure of antimicrobial metals, such as silver, nor that the materials of Nochumson could be used for anything other than electrophoretic carrier materials. Nochumson also fails to disclose lens polymers made from senofilcon A. A copy of the USAN filing for senofilcon A is attached. As shown in the USAN, senofilcon A has the following components:

Copolymer of 3-(23-butyltetracosamethyldodecasiloxanyl)propyl 2-methylprop-2-enoate (n=11), N,N-dimethylprop-2-enamide, 1-ethenylpyrrolidin-2-one, 2-hydroxyethyl 2-methylprop-2-enoate, (2RS)-2-hydroxy-3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]disiloxanyl]prooxy]propyl 2-methylprop-2-enoate and oxybis(ethyleneoxyethylene) bis(2-methylprop-2-enoate)

Polymers formed from these components are neither disclosed nor suggested by Nochumson. Nochumson also fails to disclose or suggest that the silver:ligand ratio recited in the present claims.

Vanderlaan discloses soft contact lenses formed from silicone hydrogels comprising specific monoalkyl terminated siloxane monomers (Column 2, lines 24-43). However, while Vanderlaan et al. discloses some of the same polymer components as are present in senofilcon A, Vanderlaan et al. does not disclose senofilcon A. Vanderlaan et al. also does not disclose or suggest any antimicrobial compounds, let alone the silver compounds recited in the present invention. Vanderlaan et al. also fails to disclose or suggest that the silver:ligand ratio recited in the present claims.

Examiner has provided no reasoning why someone of skill in the art looking to make an antimicrobial contact lens, would replace the antimicrobial ceramic materials disclosed in Sakuma et al. with a component from the electrophoretic gels of Nochumson. Even if such a suggestion existed, the present invention has shown surprising results sufficient to rebut it. Comparing Examples 5 through 7, it is clear that antimicrobial reductions are not possible unless the ratio of silver:ligand is in the range specified in the present application. In claims 5 through 7, the amount of silver was kept the same, but the weight % of the ligand monomer was varied. The antimicrobial efficacy *increases* as the ligand monomer concentration *decreases* and the ratio of silver to ligand *increases*. This result is not suggested by any of the references and was not expected.

Applicants respectfully submit that the rejection based upon 35 U.S.C. 103 has been traversed.

Examiner has provisionally rejected claims 1, 3-10, 12-15, and 28-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-13, 15-27 and 42-44 of copending Application No. 10/703,777, claims 1-4, and 8-35 of copending Application No. 10/715,745, and claims 1-21, 28, 40, 41 and 43 of copending Application No. 10/715,903.

Applicants respectfully submit that the present application is patentably distinct over copending application 10/703,777 (Meyers et al). Meyers et al. discloses a method for forming antimicrobial lenses comprising reacting the components “under conditions sufficient to provide a reactivity ratio of ligand monomer to at least one major lens forming component of at least about 0.45”. The ratio of silver:ligand which is recited in the present application is not suggested or disclosed.

Applicants submit a terminal disclaimer over USSN 10/715,745.

Applicants respectfully submit that the present application is patentably distinct over copending application No. 10/715,903 (“Andersson et al.”). Andersson et al. disclose antimicrobial lenses comprising at least one metal salt. Antimicrobial lenses comprising at least one ligand monomer, and the silver:ligand ratio recited in the present claims are not disclosed.

A petition for a two month extension of time is submitted herewith along with authorization to charge any fees which may be required, or credit any overpayment, to Deposit Account 10-0750/VTN0568CIP1/KAH.

Applicants respectfully submit that the foregoing amendments and arguments have traversed Examiner’s rejections. Withdrawal of the rejections, and issuance of a notice of allowance is respectfully requested.

Respectfully submitted,

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